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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,849	06/20/2003	Giovanni M. Paulctti	3715.12-1	8490

7590 10/16/2007

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,849	PAULETTI ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-45* is/are pending in the application.

4a) Of the above claim(s) *43 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-42 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/6/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention III in the reply filed on 25 July 2007 is acknowledged. The traversal is on the ground that since the examiner will be searching for the device of Invention II incorporated with or coated with the composition of claims 1-5, it would not add an additional burden on the examiner to examine claims 1-5 as well as claims 6-7, 9-11 and 21-30. This is not found persuasive because the invention of Group I is patentably distinct from the invention of Group II in that the composition of Group I can be used in another method that is materially different from the method claimed in Group II, such as sublingual administration, as discussed in the previous Official Action mailed 21 June 2007. The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of naratriptan, PEG 6000/1500, HPMC, ethoxydiglycol, a bioadhesive system and a foam for search purposes is acknowledged.

Status of Claims

Claims 1-30 were cancelled and claim 31-45 were newly added in an Amendment filed 25 July 2007. Claims 43-44 are withdrawn from consideration at this time as being drawn to a non-elected invention. As a result, claims 31-42 and 45 are examined herein on the merits for patentability. No claim is allowed at this time.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 31-42 and 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-20 of copending Application No. 11/126,863 (published as US 2005/0249774). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method for treatment of migraine, migraine headache, nausea, and vomiting associated with chemotherapy, radiotherapy, surgery, pregnancy, pre-menstrual syndrome, menstruation or menopause, with the aid of an intravaginal delivery device comprising administering said intravaginal device and a composition comprising an anti-migraine or anti-nausea drug, a mucoadhesive agent, a lipophilic or hydrophilic carrier, and a sorption promoter. Many of the anti-migraine or

anti-nausea drugs, mucoadhesive agents, lipophilic or hydrophilic carriers, sorption promoters and delivery devices are overlapping in scope, and some are identical (i.e. naratriptan, HPMC, saturated mono-, di-, or triglyceride of fatty acids having 8 to 18 carbons, PEG 6000/PEG 1500, ethoxydiglycol, and tampon, respectively). Therefore, the scope of the copending applications is overlapping, and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 31-42 and 45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 13, 15-20 and 22-23 of U.S. Patent No. 6,197,327 (hereinafter Harrison et al. '327), in view of U.S. Patent No. 6.255.502 (hereinafter Penkler et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an intravaginal drug delivery system containing an appropriate pharmaceutical agent incorporated into a pharmaceutically acceptable carrier, mucoadhesive agent, and sorption promoter, whereby the pharmaceutical agent is released into the vagina and absorbed through the vaginal mucosa. Many of the pharmaceutical agents, mucoadhesive agents, lipophilic or hydrophilic carriers, sorption promoters and delivery devices are overlapping in scope, and some are identical (i.e. ketorolac, HPMC, saturated mono-, di-, or triglyceride of fatty acids having 8 to 18 carbons, PEG 6000/PEG 1500, ethoxydiglycol, and tampon, respectively).

Harrison et al. '327 do not claim the pharmaceutical agent to comprise naratriptan. However, Penkler et al. teach naratriptan, sumatriptan and almotriptan as suitable agents for the treatment of migraines (column 7, lines 42-47; column 10, lines 47-48; and claims 1, 8) through vaginal administration (column 13, lines 4-5 and 8).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the instant invention to use naratriptan as the pharmaceutical agent in the vaginal delivery device of Harrison et al. '327, because Penkler et al. teach that naratriptan can be applied via the vagina for treatment of migraines.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,086,909 (hereinafter Harrison et al. '909).

Harrison et al. '909 disclose a method for treatment of dysmenorrhea comprising an intravaginal drug delivery system containing an appropriate pharmaceutical agent incorporated into a pharmaceutically acceptable carrier whereby the pharmaceutical

agent is released into the vagina and absorbed through the vaginal mucosa to provide relief of dysmenorrheal (abstract). Harrison et al. '909 further disclose the pharmaceutical agent to comprise aspirin, ibuprofen, ketorolac and naproxen (column 7, lines 51-53; claim 20), and the pharmaceutically acceptable carrier comprises a hydrophilic or hydrophobic carrier, such as semi-synthetic glycerides of saturated fatty acids with 8 to 18 carbons and PEG 6000/1500, respectively (column 8, lines 8-15). Also, Harrison et al. '909 disclose the pharmaceutical formulations further comprising a mucoadhesive agent, preferably hydroxypropyl methylcellulose (column 8, lines 16-22), and a penetration enhancer, preferably ethoxydiglycol (column 8, lines 23-28). Harrison et al. '909 also disclose the method of applying the pharmaceutical formulation with the aid of an intravaginal delivery device, such as tampon device, vaginal ring, pessary, tablet, vaginal suppository, vaginal sponge, bioadhesive tablet, bioadhesive microparticle, cream, lotion, foam, ointment, solution and gel (column 2, lines 37-43; column 3, lines 8-67; column 4, lines 1-27; and column 9, line 4 through column 13, line 67). Harrison et al. '909 also disclose that preferred formulations for hydrophilic drugs comprise between about 60-90% by weight lipophilic carrier, between about 5-25% mucoadhesive agent, and between about 5-20% sorption promoter, whereas preferred formulations for lipophilic drugs comprise between about 50-90% by weight hydrophilic carrier, between about 5-20% mucoadhesive agent, and between about 5-25% sorption promoter (column 8, lines 31-34 and 44-47).

2. Claims 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrison et al. '327.

Harrison et al. '327 disclose for treatment of dysmenorrhea comprise an intravaginal drug delivery system containing an appropriate pharmaceutical agent incorporated into a pharmaceutically acceptable carrier whereby the pharmaceutical agent is released into the vagina and absorbed through the vaginal mucosa to provide relief of dysmenorrheal (abstract). Harrison et al. '327 further disclose the pharmaceutical agent to comprise aspirin, ibuprofen, ketorolac and naproxen (column 6, lines 30 and 32; claims 3, 10, 13, 16, 18 and 22), and the pharmaceutically acceptable carrier comprises a hydrophilic or hydrophobic carrier, such as semi-synthetic glycerides of saturated fatty acids with 8 to 18 carbons and PEG 6000/1500, respectively (column 6, lines 52-60). Also, Harrison et al. '327 disclose the pharmaceutical formulations further comprising a mucoadhesive agent, preferably hydroxypropyl methylcellulose (column 6, lines 61-67; and claim 6), and a penetration enhancer, preferably ethoxydiglycol (column 7, lines 1-8; and claim 7). Harrison et al. '327 also disclose the method of applying the pharmaceutical formulation with the aid of an intravaginal delivery device, such as tampon device, vaginal ring, pessary, tablet, vaginal suppository, vaginal sponge, bioadhesive tablet, bioadhesive microparticle, cream, lotion, foam, ointment, solution and gel (column 7, line 51 through column 12, line 20). Harrison et al. '327 also disclose that preferred formulations for hydrophilic drugs comprise between about 60-90% by weight lipophilic carrier, between about 5-25% mucoadhesive agent, and between about 5-20% sorption promoter, whereas

preferred formulations for lipophilic drugs comprise between about 50-90% by weight hydrophilic carrier, between about 5-20% mucoadhesive agent, and between about 5-25% sorption promoter (column 7, lines 9-12 and 22-25; and claim 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 31-42 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. '909 in view of Penkler et al.

Applicant claims:

Applicants claim a method for treatment of migraine, migraine headache, nausea, and vomiting associated with chemotherapy, radiotherapy, surgery, pregnancy, pre-menstrual syndrome, menstruation or menopause, with the aid of an intravaginal delivery device comprising administering said intravaginal device and a composition

comprising an naratriptan, a mucoadhesive agent (i.e. HPMC), a lipophilic or hydrophilic carrier (mono-, di-, or triglyceride of fatty acids with 8 to 18 carbons or PEG 6000/1500, respectively) , and a sorption promoter (ethoxydiglycol).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Harrison et al. '909 teach a an intravaginal drug delivery system containing an appropriate pharmaceutical agent incorporated into a pharmaceutically acceptable carrier whereby the pharmaceutical agent is released into the vagina and absorbed through the vaginal mucosa, as discussed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Harrison et al. '909 do not teach the pharmaceutical agent to comprise naratriptan. However, Penkler et al. teach naratriptan, sumatriptan and almotriptan as suitable agents for the treatment of migraines (column 7, lines 42-47; column 10, lines 47-48; and claims 1, 8) through vaginal administration (column 13, lines 4-5 and 8).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the instant invention to use naratriptan as the pharmaceutical agent in the intravaginal delivery device of Harrison et al. '909, because Penkler et al. teach that naratriptan can be applied via the vagina for treatment of migraines.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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